

WE CLAIM:

- 1 1. An extended release pharmaceutical composition comprising
 - 2 a) a drug capable of dissociating into a valproate ion;
 - 3 b) from about 15% to about 50% w/w of a high viscosity grade hydroxypropyl
4 methylcellulose; and
 - 5 c) from about 0.1% to about 10% w/w of a low viscosity grade hydroxypropyl
6 methylcellulose.
- 1 2. The pharmaceutical composition according to claim 1, wherein the drug capable of
2 dissociating into a valproate ion comprises valproic acid and its pharmaceutically
3 acceptable salts, esters, and amides.
- 1 3. The pharmaceutical composition according to claim 2, wherein the valproic acid
2 salt comprises divalproex sodium.
- 1 4. The pharmaceutical composition according to claim 3, wherein divalproex sodium
2 comprises from about 10% to about 90% by weight of the total pharmaceutical
3 composition weight.
- 1 5. The pharmaceutical composition according to claim 1, wherein the pharmaceutical
2 composition is indicated for once a day dosing.
- 1 6. The pharmaceutical composition according to claim 1, wherein the high viscosity
2 grade hydroxypropyl methylcellulose comprises a high viscosity grade
3 hydroxypropyl methylcellulose whose 2% aqueous solution has a nominal
4 viscosity greater than about 10,000 cP.
- 1 7. The pharmaceutical composition according to claim 6, wherein the nominal
2 viscosity comprises from about 10,000 to about 100,000 cP.
- 1 8. The pharmaceutical composition according to claim 1, wherein the high viscosity
2 grade hydroxypropyl methylcellulose comprises from about 20% to about 40% by
3 weight of the total pharmaceutical composition weight.
- 1 9. The pharmaceutical composition according to claim 1, wherein the low viscosity
2 grade hydroxypropyl methylcellulose comprises a low viscosity grade

3 hydroxypropyl methylcellulose whose 2% aqueous solution has a nominal
4 viscosity less than about 1,000 cP.

1 10. The pharmaceutical composition according to claim 9, wherein the nominal
2 viscosity comprises from about 5 to about 100 cP.

1 11. The pharmaceutical composition according to claim 1, wherein the low viscosity
2 grade hydroxypropyl methylcellulose comprises from about 1% to about 5% by
3 weight of the total pharmaceutical composition weight.

1 12. The pharmaceutical composition according to claim 1, wherein the pharmaceutical
2 composition comprises a tablet or a capsule.

1 13. The pharmaceutical composition according to claim 1, wherein the extended
2 release pharmaceutical composition further comprises one or more
3 pharmaceutically inert excipients.

1 14. The pharmaceutical composition according to claim 13, wherein the one or more
2 pharmaceutically inert excipients comprise one or more of glidants, lubricants,
3 diluents and binders.

1 15. The pharmaceutical composition of claim 1, wherein the extended release
2 pharmaceutical composition is free of microcrystalline cellulose.

1 16. A process for the preparation of an extended release pharmaceutical composition,
2 the process comprising:

3 a) blending a drug capable of dissociating into the valproate ion, from about
4 15% to about 50% w/w of a high viscosity grade hydroxypropyl
5 methylcellulose and from about 0.1% to about 10% w/w of a low viscosity
6 grade hydroxypropyl methylcellulose to form a blend;

7 b) optionally granulating the blend;

8 c) lubricating the blend; and

9 d) compressing or filling into a suitable size solid dosage form.

1 17. The process according to claim 16, wherein the drug capable of dissociating as a
2 valproate ion comprises valproic acid and its pharmaceutically acceptable salts,
3 esters, and amides.

- 1 18. The process according to claim 16, wherein the drug capable of dissociating as
2 valproate ion comprises divalproex sodium.
- 1 19. The process according to claim 16, wherein the pharmaceutical composition
2 comprises a tablet or a capsule.
- 1 20. The process according to claim 16, wherein the granulation is carried out by wet
2 granulation, dry granulation or melt extrusion.
- 1 21. A method of treating mania, migraine and epilepsy in a patient in need thereof, the
2 method comprising administering an extended release pharmaceutical composition
3 comprising:
- 4 a. a drug capable of dissociating into a valproate ion;
- 5 b. from about 15% to about 50% w/w of a high viscosity grade hydroxypropyl
6 methylcellulose; and
- 7 c. from about 0.1% to about 10% w/w of a low viscosity grade hydroxypropyl
8 methylcellulose.